Medicom

Kolmi® Softex

Technical Data Sheet

M14301-30
M14311-30
M14321-30

M14311-30-2000

Medical face mask with earloops - Type II - Kolmi® Softex

Medical Device Class I

FEATURES & BENEFITS



- Protects the environment against droplets emitted by the wearer.
- Effective against bacteria, particles and viruses (tested for BFE, PFE, & VFE).
- Kolmi® masks feature the exclusive Origami fold and Smile welding for enhanced comfort and a perfect fit to the wearer's face.
- For maximum comfort, the inner layer is designed with Softex technology, which minimizes facial irritation and does not wear out during prolonged use, even in contact with a beard.
- Hypoallergenic.

Recommended use

- Use by medical staff.
- Medical masks may also be intended to be worn by patients and other individuals to reduce the risk of spreading infections, particularly in outbreak or pandemic situations.

PRODUCT DETAILS

Product name:	Kolmi® Softex Type II
Product type:	Single use, non sterile
Nose piece:	Polypropylene and steel
Size :	90 x 175 mm
Unit weight :	2,8 g
Origin :	France

Item	Color
M14301-30	White
M14311-30	Blue
M14311-30-2000	Blue
M14321-30	Green

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices.
Comply with the applicable standards EN 14683:2019 + AC: 2019.
Manufacturing site: ISO 9001 and ISO 13485 certification.

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019+AC:2019 and ISO 11737: 2018+A1: 2021.
Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

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EN 14683:2019+AC:2019					
TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2019	≥ 98% (Type II)	Centexbel	22.00525.02 09/02/2022	98,7 %
DELTA P	EN 14683:2019	< 40 Pa/cm²	Centexbel		25,1 Pa/cm²
Particles Filtration Efficiency 0,1µm : PFE	ASTM F2299	No requirements	Nelson	1393997-S01 11/03/2021	99,3 %
Viral Filtration Efficiency: VFE	ASTM F2101	No requirements	Nelson	1362438-S01 18/12/2020	99,3 %

PRECAUTIONS

The mask must be used on intact skin only.
The reuse or extended use may lead to infection or cross-contamination.
Please refer to your national legislation on the subject of disposal of this product once it has been used.

STORAGE CONDITIONS

Normal conditions of conversation & storage: not to be exposed to moisture and sunlight, must be stored at room temperature.
Shelf life of the product: 5 years.

PACKAGING MARKING

CE MD Medical Device



* Do not use if package is damaged

LOGISTICS

Outer case spec.

Item	Size (mm)	Gross weight (kg)	QTY/ pallet
M14301-30			
M14311-30	400 x 400 x 220	3,9	48
M14321-30			
M14311-30-2000	600 x 400 x 237	6,6	28

Inner box spec.

Size (mm)	Gross weight (g)	Packaging
211 x 97 x 97	215	16 boxes x 50 masks
Case of 2 000 pieces in one bag		

EAN Codes

Item	Outer case	Inner box
M14301-30	3 662 036 012 173	3 662 036 012 180
M14311-30	3 662 036 012 197	3 662 036 012 203
M14311-30-2000	3 662 036 012 272	/
M14321-30	3 662 036 012 210	3 662 036 012 227

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